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UNITED STATES DEPARTMENT OF COMMERCE

Patent and Trademark Office

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FEB 11 1993

Dr. L.A. Nielsen
Burroughs Wellcome Co.
3030 Cornwallis Road
Research Triangle Park, NC 27709

Re: Patent Term Extension
Application for
U.S. Patent No. 4,761,418

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,761,418 issued August 2, 1988, which claims the human drug product Mivacron, is eligible for patent term extension under 35 USC § 156. The period of extension has been determined to be 173 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of January 27, 1993. The January 27, 1993, notice corrected an original notice of the regulatory review period published in the Federal Register of June 2, 1992. Under 35 USC § 156 (c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 \text{ (Testing Phase)} + \text{Approval Phase} \\ &= 1/2 (760) + 511 \\ &= 891 \text{ days}\end{aligned}$$

Since the regulatory review period began July 7, 1984, before the patent issue date, only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period. The period of time from the start of the regulatory review period on July 7, 1984, up to the issuance of the patent on August 2, 1988, is 1,486 days. This period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: $2,246 - 1,486 = 760$ days. No determination of a lack of due diligence was made.

The 14 year exception of 35 USC § 156 (c)(3) operates to limit the term of extension in the present situation because it provides that the period remaining in the term of the patent measured after the date of approval of the approved product (January 22, 1992) when added to the period of extension calculated above (891 days) cannot exceed fourteen years. The period of extension is thus limited to January 22, 2006, by operation of 35 USC § 156 (c)(3). Since the patent term of seventeen years (35 USC § 154) would expire on August 2, 2005, the period of extension is the number of days to extend the term of the patent from its expiration date to and including January 22, 2006, or 173 days.

The limitations of 35 USC § 156 (g)(6) do not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136 (a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,761,418 a certificate of extension, under seal, for a period of 173 days.

Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent No.:	4,761,418
Granted:	August 2, 1988
Applicant:	Roy A. Swaringen, Jr. et al
Owner of Record:	Burroughs Wellcome Co.
Title:	NOVEL COMPOUNDS
Classification:	514/308
Product Trade Name:	Mivacron
Term Extended:	173 days

C. E. Van Horn

Charles E. Van Horn
Patent Policy & Projects Administrator
Office of the Assistant Commissioner for Patents

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

RE: Mivacron
FDA Docket No.: 92E - 0156